

## Program Project Description:

The primary federal law that governs how the EPA oversees pesticide manufacture, distribution and use in the United States is the [ [HYPERLINK "http://www.epa.gov/pesticides/bluebook/FIFRA.pdf"](http://www.epa.gov/pesticides/bluebook/FIFRA.pdf) ]. Originally enacted in 1947, this law has been significantly amended several times, most recently by the [ [HYPERLINK "http://www.epa.gov/pesticides/regulating/laws/fqpa/index.htm"](http://www.epa.gov/pesticides/regulating/laws/fqpa/index.htm) ] and the Pesticide Registration Improvement Extension Act of 2012 (PRIA3). FIFRA requires that the EPA register pesticides based on a finding that they will not cause unreasonable adverse effects on people and the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. Each time the law has been amended, while Congress has strengthened the safety standards of the act, it continues to recognize the benefits of pesticides.

This program seeks to realize the value of pesticides that can be used safely to yield many benefits – among them, to generate the nation’s abundant and wholesome food supply, to protect the public from disease-carrying pests, to protect our environment from the introduction of invasive species from other parts of the world, to kill viruses and bacteria in America’s hospitals, and to protect the nation’s homes and schools from invasive insects, rodents, molds, and other unwelcome guests.

### *Addressing Special Local Needs*

FIFRA Section 24(c), and the EPA’s implementing regulations give states the authority to issue their own state-specific registrations under certain conditions, while the EPA is responsible for overseeing the general program. States may register a new end use product or an additional use of a federally registered pesticide product if the following conditions exist:

- A Special Local Need – an existing or imminent pest problem within a state for which the state lead agency, based on satisfactory supporting information, has determined that an appropriate federally registered pesticide product is not sufficiently available.
- The additional use is covered by any necessary tolerances (maximum legal residue levels) or other clearances under the Federal Food, Drug, and Cosmetic Act (FFDCA).
- Registration for the same use has not previously been denied, disapproved, suspended, or canceled by the EPA or voluntarily canceled by the registrant subsequent to issuance of a notice of intent to cancel because of health or environmental concerns.
- Registration is in accord with the purposes of FIFRA.

These 24(c) registrations become federal registrations in 90 days unless the EPA objects to them. The EPA's role is to ensure that each 24(c) registration meets the requirements of FIFRA.<sup>1</sup>

### *Emergency, Quarantine, and Crisis Exemptions*

FIFRA Section 18, and the EPA’s implementing regulations, authorize the EPA, in the event of an emergency, such as a severe pest infestation, to allow an unregistered use of a pesticide for a

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<sup>1</sup> [ [HYPERLINK "http://www.epa.gov/opprd001/24c/"](http://www.epa.gov/opprd001/24c/) ]

limited time if the EPA determines that emergency conditions exist which require such an exemption.<sup>2</sup>

An “Emergency Condition” is an urgent, non-routine situation that requires the use of a pesticide(s). Emergency exemptions may be requested by any state or federal agency, but typically come from state lead agricultural agencies. The EPA also must establish any necessary tolerances to cover pesticide residues in food, if applicable. Tolerances established for emergency exemption uses are time-limited, corresponding to the time that commodities treated under the exemption might be found in channels of trade.

A second type of emergency exemption is allowed for “public health” emergencies. A state or federal agency may request a public health emergency exemption to control a pest that will cause a significant risk to human health.

The third type of exemption, the “Quarantine” exemption, is allowed to control the introduction or spread of an invasive pest species not previously known to occur in the United States and its territories.

Finally, when the emergency is so immediate that there is not enough time to go through the normal review for an exemption and there is an immediate need, following communication with clearance by the EPA, a state or federal agency may issue a “crisis exemption” allowing the unregistered use to proceed for up to 15 days. During the consultation before the state or federal agency declares a crisis, the EPA performs a review to determine whether there are any apparent concerns, and whether the appropriate safety findings required by FIFRA likely may be made. If the EPA identifies concerns, the crisis exemption may not be allowed unless those concerns can be resolved.

#### *Meeting Agriculture’s Need for Safe, Effective Pest Control Products*

With the passage of FQPA, Congress acknowledged the importance of and need for “reduced-risk pesticides” and supported expedited agency review to help these pesticides reach the market sooner and replace older and potentially riskier chemicals. The law defines a reduced risk pesticide as one that “may reasonably be expected to accomplish one or more of the following: (1) reduces pesticide risks to human health; (2) reduces pesticide risks to non-target organisms; (3) reduces the potential for contamination of valued, environmental resources, or (4) broadens adoption of Integrated Pest Management (IPM)<sup>3</sup> or makes it more effective.” The EPA developed procedures and guidelines for expedited review of applications for registration or amendments for a reduced risk pesticide. The agency expanded the reduced risk pesticide program to include consideration of new active ingredients, new uses of active ingredients already deemed to be reduced risk, and amendments to all uses deemed to be reduced risk. The EPA gives priority to review of reduced risk pesticides and works with the regulated community and user groups to refine review and registration procedures.

#### *FIFRA’s Version of “Generic” Pesticides*

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<sup>2</sup> [ HYPERLINK "<http://www.epa.gov/opprd001/section18/>" ]

<sup>3</sup> [ HYPERLINK "<http://www.epa.gov/pesticides/factsheets/ipm.htm>" ] )

FIFRA authorizes the EPA to register products that are identical to or substantially similar to already registered products (known as “me too” products). Applicants for these substantially similar products may rely on, or “cite” (and offer to pay a fair share for) data already submitted by another registrant. The entry of these new products into the market can cause price reductions resulting from new competition and broader access to products. These price declines generate competition that benefits farmers and other consumers.

### *“Minor Crops” – Addressing Growers’ Need for Pest Control*

The FQPA amendments made special provisions for minor uses of pesticides. Minor uses of pesticides are defined as uses for which pesticide product sales do not provide sufficient economic incentive to justify the costs of developing and maintaining its registrations with the EPA. “Minor” crops include many fruits and vegetables. Minor uses also include use on commercially grown flowers, trees and shrubs, certain applications to major crops such as wheat or corn where the pest problem is not widespread, and many public health applications<sup>4</sup>.

Some minor uses have been lost through lack of registrant support during the reregistration process, resulting in grower concerns that adequate pest control tools will no longer be available for many minor crops. The agency works closely with the USDA’s Inter-Regional Research Project No. 4 (IR-4)<sup>5</sup> to generate residue data for tolerances on minor crops in order to minimize the burden of data generation for minor uses. The EPA and the USDA operate early alert systems to notify growers when a pesticide use for a minor crop is about to be canceled. The EPA provides advance public notice of a proposed cancellation to allow time for another registrant to consider maintaining the pesticide use.

### *Meeting the Need for Non-agricultural Pesticides*

Farmers are not the only ones who need pesticides. Pest control also is needed in our homes, schools, and workplaces. Pesticides control pests that spread disease like West Nile Virus, malaria and rabies, to name a few. They disinfect our swimming pools and sanitize bathrooms; they combat mold and are essential to sterilize surfaces in hospitals and other health care facilities.

### *Outreach and Education*

The agency will continue to encourage Integrated Pest Management (IPM), which emphasizes minimizing the use of broad spectrum chemicals and maximizing the use of sanitation, biological controls, and selective methods of application, and it relies on pesticide users being well-informed about the pest control options available and how to best use them. It is not enough to have pesticide products registered to control pest infestations. Pesticide users need to know which pesticides to use, how to use them, and how to maintain the site, so pests do not return. The Pesticide Program is invested in outreach and training efforts for people who use pesticides and the public in general.

### **FY 2018 Activities and Performance Plan:**

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<sup>4</sup> [ HYPERLINK "[http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa\\_accomplishments.htm](http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_accomplishments.htm)" ]

<sup>5</sup> [ HYPERLINK "[http://www.csrees.usda.gov/nea/pest/in\\_focus/pesticides\\_if\\_minor.html](http://www.csrees.usda.gov/nea/pest/in_focus/pesticides_if_minor.html)" ] ]

The EPA's statutory and regulatory functions for the pesticide program include registration, product reregistration, registration review, risk reduction, rulemaking, and program management. During FY 2018, the EPA will review and register new pesticides, new uses for existing pesticides, and act on other registration requests in accordance with FIFRA and FFDCA standards as well as PRIA3 timeframes. Many of these actions will be for reduced-risk pesticides, which, once registered and used by consumers, will increase benefits to society. Working together with the affected user communities, through IPM and related activities, the agency plans to accelerate the adoption of these lower-risk products.

The EPA will continue to support implementation of other IPM-related activities. The agency will engage partners in the development of tools and informational brochures to promote IPM efforts and to provide guidance to schools, farmers, other partners, and stakeholders.

Similarly, the agency will continue its work-sharing efforts with its international partners. Through these collaborative activities and resulting international registrations, international trade barriers will be reduced. When nations with whom we trade accept imported crops treated with newer, lower-risk pesticides, domestic users can more readily adopt these newer pesticides into their crop protection programs. Work-sharing efforts also reduce the costs of registration to governments sharing the expenses.

The Section 18 Program provides exemptions to allow growers to use pesticides needed to combat emergency situations. In FY 2018, the EPA will continue to prioritize emergency exemptions. The economic benefit of the Section 18 Program to growers is the avoidance of losses incurred in the absence of pesticides exempted under FIFRA's emergency exemption provisions.

**Performance Targets:**

# Deliberative Process / Ex. 5

**Statutory Authority:**

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Federal Food, Drug, and Cosmetic Act (FFDCA), §408.